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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,664	10/29/2003	William Gartner	340885.90013	4235

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EXAMINER

SUHOL, DMITRY

ART UNIT	PAPER NUMBER
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3714

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/694,664

Applicant(s)

GARTNER ET AL.

Examiner

Dmitry Suhol

Art Unit

3714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-17 and 20 is/are rejected.
- 7) ☒ Claim(s) 8, 9, 18 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Recent progress in the development of a clinically useful microencapsulated olfactory function test" by Doty et al (here from referred to as RPDOT) in view of Cotman (WO 89/00398) and Rugland et al '689. RPDOT discloses an olfactory test for self-administered screening of olfactory disorders indicative of a variety of diseases containing most of the elements of the claims including, a plurality of odor containing sources as required by claim 1 (page 5, last paragraph), each odor-containing source containing a familiar odor as required by claim 1 (page 6, last sentence in second paragraph), a plurality of labels located adjacent to each of the odor-containing sources and providing choices of possible identity of the odor-containing source as required by claim 1 (page 6, first paragraph). Four labels being provided for each odor-containing source, as required by claim 5, are described on page 6, first paragraph. A plurality of labels for each odor-containing source being distinctly different from each other, as required by claim 6, described in the first paragraph on page 6. A plurality of odor-

containing sources being distinctly different from each other, as required by claim 7, is described on page 5 in the last paragraph and on page 6 in the second paragraph.

RPDOT lacks an explicit teaching of an removably covered answer key as required by claim 1 utilizing a sealed cover sheet (as required by claim 4), a first, second (as required by claim 3) and third instruction for self-administering, self-scoring, and self-interpreting the olfactory test as required by claim 1, an odor containing source having a unique distinguishing feature, as required by claims 10, a neurological disease being Alzheimer's as required by claim 11, and a first sheet with an instruction for a medical professional as required by claim 12. However, Rugland discloses a multiple choice test (as does RPDOT) which teaches that it is known to provide a removably covered answer key (12) utilizing a sealed cover sheet (figure 1). Cotman discloses a kit for olfactory testing which teaches providing instructions for self-scoring the olfactory test (page 8, lines 1-4) in order to diagnose a possible onset of Alzheimer's disease (as required by claim 11) (page 8, lines 5-6). Cotman further teaches an odor containing source having a unique distinguishing feature (figure 2, element 1). Therefore it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to provide a removably covered answer key and instructions with the test of RPDOT for the purpose of positive identification and interpretation of the results of the test and for preventing the examinee from gaining access to the scoring sheet, especially since the booklet of RPDOT is concerned with self-administration of the olfactory test (see RPDOT page 5, second paragraph, first sentence). It would have

Art Unit: 3714

been further obvious to provide a unique distinguishing feature on the odor source for the purpose of clear identification of the location of the source.

Regarding the specifics of the first, second and third instructions as required by claims 1, 2, 3 and 12, it would have been obvious to provide a first, second and third instruction with the specifics of claims 1, 2, 3 and 12 since it would only depend on the intended use of the assembly and the desired information to be displayed. Further, it has been held that when the claimed printed matter is not functionally related to the substrate it will not distinguish the invention from the prior art in terms of patentability. *In re Gulack*, 217 USPQ 401, (CAFC 1983). The fact that the content of the printed matter placed on the substrate may render the device more convenient by providing an individual with a specific type of instruction does not alter the functional relationship. Mere support by the substrate for the printed matter is not the kind of functional relationship necessary for patentability. Thus, there is no novel and unobvious functional relationship between the printed matter (e.g. instructions) and the substrate (e.g. olfactory test) which is required for patentability.

Regarding the specific layout as required by claims 8 and 9, the examiner takes official notice that such an arrangement of labels and odor-containing sources is utilized in the UPSIT described in the RPDOT reference.

An instrument for recording the possible identity of an odor-containing source (as required by claim 13) would have been obvious since examiner takes official notice of such devices being well known in the art (i.e. a pen, and a piece of plastic).

Claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Recent progress in the development of a clinically useful microencapsulated olfactory function test" by Doty et al (here from referred to as RPDOT) in view of Cotman (WO 89/00398), Rugland et al '689 and Buschke '629. RPDOT, as modified by Cotman and Rugland, discloses most of the elements of the claims, as stated above, but for the steps of self-administering, self-scoring and self-interpreting the test without the assistance from a medical professional as required by claim 14. However, Buschke discloses a medical test device for the determination of Alzheimer's which teaches that it is known to provide an at home self-test which allows for self-administration, self-scoring and self-interpreting the results of the test without the help of a medical professional (col. 2, lines 37-39 and col. 5, lines 28-33). Therefore it would have been obvious to incorporate the steps of self-administering, self-scoring and self-interpreting with the test of RPDOT without the assistance from a medical professional for the purpose of providing a reliable, rapid test for self-testing at home or elsewhere, especially since RPDOT clearly teaches that their test is self-administered (RPDOT, page 5, second paragraph) and since self administered medical tests, scoring and interpretation thereof without the need for a medical professional are notoriously well known in the art (e.g. home pregnancy tests, diabetic test kits and others).

Allowable Subject Matter

Claims 8-9 and 18-19 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments, see applicants arguments pages 5-6, filed November 2nd, 2004, with respect to the rejection(s) of claim(s) 1-3 and 5-20 under 35 USC 103(a) incorporating the Ladd '139 reference have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Rugland et al '689 and Buschke '629. It should be noted that with respect to applicants argument that RPDOT does not disclose a self-administered screening of neurological disease but rather a self-administered mass screening procedure for diagnosing smell dysfunctions, the examiner points out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). However, even if the above intended use limitation is given patentable weight it is pointed out that RPDOT clearly points to the

Art Unit: 3714

fact that olfactory disorders are known to occur do to a variety of conditions and are important diagnostic signs of a number of disorders:

It is well known to otorhinolaryngologists that olfactory disorders occur as a result of accidents, disease states, medical interventions, aging and exposure to environmental pollutants. Furthermore, it is now evident that such problems can serve as important diagnostic signs of a number of serious diseases and anomalies, including ones associated with ontogeny of the hypothalamus and pituitary, intracranial neoplasms, and temporal lobe epilepsy.

While Cotman clearly links olfactory function with Alzheimer's disease. Therefore when both references are looked upon as a whole it is clear that RPDOT does in fact disclose a self-administered screening procedure for neurological disease.

With respect to applicants assertion that Cotman fails to teach an olfactory test that does not require the assistance of a medical professional for administration, scoring and interpretation of the test, and that odor sources of Cotman are not ordinarily experienced by the user, it is pointed out that RPDOT already discloses a self-administered olfactory test and odors which are familiar to the user, while the Cotman is only relied upon to teach providing instructions for the self-scoring/interpretation of test results like that of RPDOT and the use of an odor containing source having a unique distinguishing feature (see above rejection).

Regarding applicants arguments with respect to the instructions and information contained therein (i.e. In re Gulack rejection), the examiner maintains his rejection that there is no novel and unobvious functional relationship between the printed matter (e.g. instructions) and the substrate (e.g. olfactory test) which is required for patentability since the printed matter in no way depends on the kit and the kit in no way depends on the printed matter (*In re Ngai*, 70 USPQ2d 1862 (Fed. Cir. 2004)).

Regarding the rejections with respect to claims 8-9 and 18-19, the rejections have been withdrawn and the claims have been indicated to be allowable.

Regarding applicants arguments that there is no suggestion to combine the Rugland reference with RPDOT and Cottman, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, RPDOT discloses a multiple choice type self-administered test but lacks the answer key which is removably covered by a sealed cover sheet. Rugland teaches that it is known to provide a self administered test which incorporates an answer key covered by a sealed cover for the purpose of positive identification and interpretation of the results of the test and for preventing the examinee from gaining access to the scoring sheet (col. 1, lines 30-35). Therefore since RPDOT clearly discloses a self-administered test incorporating an answer sheet for the purpose of positive identification and interpretation of the results of the test and for preventing the examinee from gaining access to the scoring sheet is clearly pointed to in both references (RPDOT and Rugland).

Regarding applicants arguments that Rugland does not teach an olfactory test for self-screening neurological diseases that does not require the assistance of a medical professional for administration, scoring and interpretation of the test, a booklet with odor

Art Unit: 3714

sources and instructions, the examiner agrees but points out that Rugland is merely relied upon to teach that it is known to provide a sealed answer sheet with self-administered test, while the above features are clearly taught by the combination of RPDOT and Cottman (see above rejection).

Regarding applicants arguments that Buschke '629 fails to teach any form of a test for self-screening neurological diseases which may be self interpreted without the assistance of a medical professional, the examiner points out that Buschke clearly indicates at col. 1, lines 10-23 that devices such as his may indicate a further need to test for dementia (e.g. Alzheimer's, or a neurological disease). Buschke further discloses that method steps involved in such testing (at least initial testing) are known to be performed at home without the need of a medical professional (col. 2, lines 37-39 and col. 5, lines 28-33) also see tables listed at cols. 11-12 for results with scoring and interpretation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dmitry Suhol whose telephone number is 571-273-4430. The examiner can normally be reached on Mon - Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Derris Banks can be reached on 703-308-1745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ds

Dmitry Suhov
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